

*Attachment 3 (Exhibit B) to Resolution Agreement
United States v. Indivior Inc. and Indivior plc*

Information

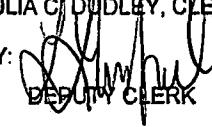
UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA)
) Criminal No. 1:20CR00027
v.)
) Violations: CLERK'S OFFICE U.S. DISTRICT COURT
INDIVIOR SOLUTIONS, INC.) 18 U.S.C. § 1035 AT ABINGDON, VA
) FILED
)

INFORMATION

JUL 24 2020

COUNT ONE
False Statements Relating to Health Care Matters
18 U.S.C. § 1035

JULIA C. DUDLEY, CLERK
BY: 
DEPUTY CLERK

The Attorney for the United States¹ charges that:

DEFENDANT

1. INDIVIOR SOLUTIONS, INC. (hereinafter "INDIVIOR SOLUTIONS") is a wholly owned subsidiary of Indivior Inc., which was previously known as Reckitt Benckiser Pharmaceuticals Inc. ("RBP"). INDIVIOR SOLUTIONS was a division of RBP until it became a subsidiary corporation in September 2013. INDIVIOR SOLUTIONS is a Delaware corporation headquartered in Richmond, Virginia.

2. At times relevant to this Information, INDIVIOR SOLUTIONS was engaged in the pharmaceutical business throughout the United States, including in the Western District of Virginia. INDIVIOR SOLUTIONS' business included marketing, promotion, field sales, managed-care sales, and field-medical functions for drugs containing buprenorphine, an opioid, under brand names including Suboxone and Subutex.

¹ Authority conferred by 28 U.S.C. § 515.

3. Until December 2014, RBP and INDIVIOR SOLUTIONS were subsidiaries of Company A.

HEALTH CARE BENEFIT PROGRAMS

4. Medicaid is a health care benefit program under Title 18, United States Code, Section 24(b) that was administered by agencies of the various states to provide health care benefits and services to those who qualified. Medicaid is funded jointly by the states and by CMS and paid for certain prescription drugs for Medicaid beneficiaries.

5. MassHealth is the name of the Commonwealth of Massachusetts Medicaid program.

SUBOXONE TABLET AND SUBUTEX TABLET

6. Opioid addiction/dependence was and is an epidemic. Some individuals seeking to recover from opioid addiction/dependence continued taking opioids under medical supervision to avoid or reduce withdrawal symptoms while they sought to recover. The only opioid approved for use in such treatment outside a treatment clinic (*i.e.*, that a patient could take at home) was buprenorphine, a Schedule III controlled substance under the Controlled Substances Act.

7. On or about October 8, 2002, RBP received approval from the Food and Drug Administration (“FDA”) for the first buprenorphine-containing drugs for use in the treatment of opioid addiction/dependence: Suboxone Sublingual Tablet (“Suboxone Tablet”) and Subutex Sublingual Tablet (“Subutex Tablet”). The FDA designated both as orphan drugs, meaning the FDA committed not to approve any competitor drug for seven years (the “exclusivity period”).

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8. Suboxone Tablet contained buprenorphine and another substance, naloxone. Suboxone Tablet was intended to be taken by placement under the tongue until dissolved. The naloxone generally was not active when taken under the tongue as intended, but it could precipitate withdrawal if the drug were taken in other ways (e.g., injected). Pharmacies typically dispensed Suboxone Tablet in bottles with child-resistant caps.

9. Subutex Tablet was similar to Suboxone Tablet, but it did not include naloxone. It was intended for induction and certain patient populations, such as patients hypersensitive to naloxone. Pharmacies typically dispensed Subutex Tablet in bottles with child-resistant caps.

SUBOXONE FILM

10. In 2007, as Suboxone Tablet and Subutex Tablet neared the end of their period of exclusivity, RBP began developing a new buprenorphine-containing drug for use in opioid addiction/dependence treatment: Suboxone Sublingual Film (“Suboxone Film”).

11. Like Suboxone Tablet, Suboxone Film was a combination of buprenorphine and naloxone, but because aspects of the film formulation were patented, it arguably had patent protection.

12. Suboxone Film differed from Suboxone Tablet in that (among other things) it has a thin form; sticks to the tongue/mouth; dissolves more rapidly; has potentially greater relative bioavailability at certain doses (as stated in the FDA-approved label); is formulated to taste better; and is packaged in individually wrapped, child-resistant foil pouches.

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13. In August 2010, RBP received approval from the FDA to market Suboxone Film for use in the treatment of opioid addiction/dependence.

14. At times relevant to this Information, INDIVIOR SOLUTIONS marketed Suboxone Film to physicians and healthcare programs throughout the United States, including the Western District of Virginia

PEDIATRIC EXPOSURE RISK

15. Suboxone Tablet, Subutex Tablet, and Suboxone Film, like many other drugs, carry a risk to children who take them by accident, sometimes called “unintended pediatric exposure.” This risk of unintended pediatric exposure is identified in the Important Safety Information in Suboxone’s FDA-approved labeling, on its package, and in a Medication Guide and Physician Brochure with instructions on safe storage of the drug.

16. INDIVIOR SOLUTIONS and others received data from poison control centers on unintended pediatric exposure for all buprenorphine drugs. During 2012 and thereafter, the data were analyzed by the Researcher Abuse, Diversion, and Addiction-Related Surveillance System (“RADARS”) for rates and trends.

17. INDIVIOR SOLUTIONS used RADARS analyses of unintended pediatric exposure to buprenorphine drugs in the marketing of Suboxone Film. Specifically, INDIVIOR SOLUTIONS used RADARS analyses to assert that Suboxone Film provided greater protection against unintended pediatric exposure than other, similar drugs.

MATERIALLY FALSE STATEMENTS TO MASSHEALTH OFFICIALS

18. Before in or around December 2012, Suboxone Film was not a preferred drug on the MassHealth formulary and had restrictions on approval for reimbursement. To increase sales of Suboxone Film, INDIVIOR SOLUTIONS employees and agents sought to persuade MassHealth that Suboxone Film had safety benefits compared to other, similar drugs, in an effort to make Suboxone Film a preferred drug on the MassHealth formulary and boost profits.

19. On or about May 17, 2011, a purported physician, acting at the behest of INDIVIOR SOLUTIONS State Government Affairs employees submitted an Op-Ed Letter to The Boston Globe, The Boston Herald, and The Patriot Ledger, stating that Suboxone Film was “preventing diversion, recidivism, and the accidental death of inquisitive children,” and by declining to provide Medicaid coverage of Suboxone Film, MassHealth officials were “engaging in 21st century biological warfare, no different than giving small pox infected blankets to the Indians.”

20. On or about June 23, 2011, the same purported physician, again acting at the behest of INDIVIOR SOLUTIONS State Government Affairs employees, sent an unsubstantiated email to MassHealth officials stating, “there is less opportunity for diversion with” Suboxone Film, “there is less chance that a curious child will ingest the film,” and “the inaction by the policy makers of MassHealth can be seen just as Strom Thurmond’s filibuster in opposition of the Civil Rights Act of 1957.” The purported physician subsequently emailed the INDIVIOR SOLUTIONS State Government Affairs employees, seeking a \$30,000 donation to his foundation and a Harley-Davidson Road

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King motorcycle as payment. The INDIVIOR SOLUTIONS State Government Affairs employees declined to make such payments.

21. On or about October 9, 2012, INDIVIOR SOLUTIONS Medical Affairs Manager met with a MassHealth official, and provided a RADARS analysis of unintended pediatric exposure data from poison control centers nationwide. After the meeting, the INDIVIOR SOLUTIONS Medical Affairs Manager asked RADARS for an analysis of unintended pediatric exposure data for Massachusetts only, *i.e.*, a Massachusetts-specific analysis, to provide to the MassHealth official.

22. The next day, on or about October 10, 2012, RADARS provided the INDIVIOR SOLUTIONS Medical Affairs Manager with the Massachusetts-specific analysis. It stated the rates of unintended pediatric exposure in Massachusetts for three categories of drugs: Suboxone Film, Suboxone Tablet, and buprenorphine-only tablets such as Subutex Tablet (sometimes called “mono tablets”). It stated that in Massachusetts there were 1.8 exposures per 10,000 units for buprenorphine-only tablets such as Subutex Tablet, 3.3 exposures per 10,000 units for Suboxone Tablets, and 2.7 exposures per 10,000 units for Suboxone Film. These data showed that buprenorphine-only tablets like Subutex Tablet—which are packaged in bottles with child-resistant caps; in the same manner as Suboxone Tablet and many other drugs—had the lowest rate of unintended pediatric exposure among the three categories in Massachusetts.

23. Upon receiving the analysis, the INDIVIOR SOLUTIONS Medical Affairs Manager asked RADARS (copying RBP’s Global Medical Director) if she could “just add

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the mono and combination tablets to see the difference from film.” However, adding the rates together would not provide an accurate calculation.

24. On or about October 16, 2012, the INDIVIOR SOLUTIONS Medical Affairs Manager sent the MassHealth official an email containing false and misleading statements. The email contained a calculation of the unintended pediatric exposure data for Massachusetts that in fact added the two tablet rates together. Further, the INDIVIOR SOLUTIONS Medical Affairs Manager indicated to the MassHealth official that she had received the calculations from RADARS, when in fact, she had not received them from RADARS, but had done them herself. The INDIVIOR SOLUTIONS Medical Affairs Manager stated to the MassHealth official, and her calculations appeared to show, that Suboxone Film had the lowest rate of unintentional pediatric exposure in Massachusetts, when in fact, buprenorphine-only tablets like Subutex Tablet had the lowest rate in Massachusetts. The INDIVIOR SOLUTIONS Medical Affairs Manager then forwarded this email to RBP’s Global Medical Director, stating that she sent it to “help us get some movement in Mass.”

25. Subsequently, the INDIVIOR SOLUTIONS Medical Affairs Manager received additional unintended pediatric exposure data that did not show that Suboxone Film had the lowest rate of unintended pediatric exposure in Massachusetts, and did not provide it to MassHealth. At an RBP corporate conference, the INDIVIOR SOLUTIONS Medical Affairs Manager told other INDIVIOR SOLUTIONS employees that her rationale for withholding the additional data from MassHealth was, “don’t ask, don’t tell.”

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26. In or about December 2012, MassHealth issued a press release announcing that it would “provide access to the unit-dosed film formulation to those members prescribed Suboxone who live in households with children less than six years of age,” and citing to INDIVIOR SOLUTIONS’ nationwide pediatric exposure rate data.

27. INDIVIOR SOLUTIONS failed to correct its inaccurate, false, and misleading statement made to MassHealth about unintended pediatric exposure in Massachusetts until December 2015, after the government had seized documents related to the false statements in a search warrant executed at RBP’s Richmond, Virginia, headquarters. During an intervening period between December 2012 and December 2015, MassHealth reimbursed at least a portion of the cost for Suboxone Film prescriptions written for certain of its beneficiaries, all to the benefit of INDIVIOR SOLUTIONS.

28. Therefore on dates set forth in this Information, in the Western District of Virginia and elsewhere, the defendant

INDIVIOR SOLUTIONS, INC.

knowingly and willfully made materially false statements to MassHealth in connection with the delivery of and payment for health care benefits, items, and services, all in violation of Title 18, United States Code, Section 1035.

NOTICE OF FORFEITURE

1. Upon conviction of the offense alleged in this Information, INDIVIOR SOLUTIONS shall forfeit to the United States property that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of knowingly and

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willfully making false statements relating to health care matters in violation of 18 U.S.C. § 1035, pursuant to 18 U.S.C. § 982(a)(7).

2. The property to be forfeited to the United States is a forfeiture money judgment of up to \$289,000,000 (Two Hundred Eighty-Nine Million Dollars) pursuant to 18 U.S.C. § 982(a)(7) and 28 U.S.C. § 2461(c), in that such sum in aggregate was obtained directly or indirectly as a result of said offenses or is traceable to such property.

3. If any of the above-described forfeitable property, as a result of any act or omission of the defendant:

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with a third person;
- c. has been placed beyond the jurisdiction of the Court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be subdivided without difficulty.

it is the intent of the United States to seek forfeiture of any other property of the defendant up to the value of the above-described forfeitable property, pursuant to 21 U.S.C. § 853(p).

Dated:

Daniel P. Bubar
First Assistant United States Attorney
Attorney for the United States, Acting Under Authority Conferred by 28 U.S.C. § 515

Gustav W. Eyler
Director
Consumer Protection Branch
United States Department of Justice

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Authorized Corporate Officer's Initials: 

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Dated:

Daniel P. Bubar
First Assistant United States Attorney
Attorney for the United States, Acting Under Authority Conferred by 28 U.S.C. § 515

Gustav W. Eyley
Director
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Seen and Agreed to:

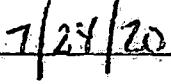
Indivior Solutions, Inc.

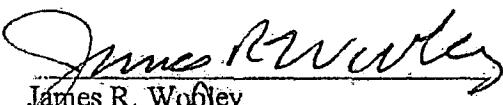
BY:


Javier Rodriguez

Authorized Corporate Representative
for Indivior Solutions, Inc.

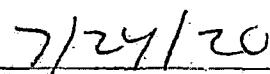
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James R. Wooley

Counsel for Indivior Solutions, Inc.

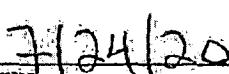
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Thomas W. Beimers

Counsel for Indivior Solutions, Inc.

DATE



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